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Artificial Heart Research: An Historical Perspective

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Food and Drug Law

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Introduction

From the beginnings of time, the human heart has continually occupied a central position within the world's varied cultures. This centrality is illustrated by the numerous ways in which references to the heart pervade contemporary language and discourse. A resilient soul who refuses to cower in the face of adversity is said to have the "heart of a lion." Persons characterized by extreme generosity are deemed to have "hearts of gold." Those who fail at romance suffer from "broken" hearts. Viewed as a symbol of love, compassion, courage, and countless other higher order human aspirations, the sacred heart will forever serve an unsurpassed metaphoric role within our lives.

While the cultural and social significance of the heart is almost immeasurable, its scientific traits are no less staggering. Weighing a mere pound, and occupying as much space as a clenched fist, the heart shoulders the responsibility for pumping blood throughout the entire human circulatory system.¹ The circulatory system

¹See *Heart, How it Works*, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/hworks.html (April 6, 2001)

delivers much needed oxygen and nutrients to the organs and tissues of the body, and then returns depleted blood to the heart and the lungs for regeneration.² This perpetual cycle represents the scientific essence of human life. On an average day, the heart will “beat”, i.e. expand and contract, nearly 100,000 times, while pumping about 2000 gallons of blood.³ In a 70-year lifetime, a normal heart will beat more than 2.5 billion times.⁴

Given the arduous physical demands placed on the human heart, it should come as no surprise that heart disease represents one of society’s gravest health risks. Essentially, heart disease is present when the pumping and circulatory functions described above encounter interference. Although heart disease comes in myriad forms, its variations can be grouped into two basic categories. “Congenital” heart disease involves organ defects that are inborn, or existent at birth.⁵ These defects may impede the flow of blood in the heart or in the vessels near it.⁶ Furthermore, the defects may cause blood to flow through the heart in abnormal patterns.⁷ “Congestive” heart failure, on the other hand, doesn’t necessarily involve inborn organ defects. Rather, this condition is present when the heart’s pumping function is restricted by an underlying medical condition that has developed over time, such as clogged arteries or high blood pressure.⁸

Congenital and congestive forms of heart disease take an enormous toll on society. As noted previously, the heart’s pumping action supplies the body with the oxygen and nutrient-rich blood it needs in order to function properly.⁹ Persons plagued by early and middle stage heart disease suffer from a shortage of these life-sustaining elements. Thus, such persons often tend to feel weak, fatigued, and short of breath.¹⁰ As

²Id.

³Id.

⁴Id.

⁵See *Congenital Cardiovascular Disease*, at http://www.americanheart.org/Heart_and_Stroke_A_Z_GuId.e/conghd.html (April 6, 2001)

⁶Id.

⁷Id.

⁸See *Congestive Heart Failure*, at http://www.americanheart.org/Heart_and_Stroke_A_Z_GuId.e/congest.html (April 6, 2001)

⁹See *Understanding Heart Failure*, at <http://www.americanheart.org/chf/understanding/index.htm> (April 6, 2001)

¹⁰Id.

the American Heart Association notes, basic daily activities such as walking, climbing stairs, and carrying groceries can begin to feel like insurmountable tasks for patients suffering within this category.¹¹

While the productivity and lifestyle-related losses that stem from early and middle stage heart disease are quite substantial, the terrifying impact of this health condition is most clearly illustrated by the experiences of those suffering at the end-stage of the disease. Each year, nearly 1,000,000 people die from complications of cardiovascular disease.¹² Indeed, according to some experts, heart disease kills as many persons as nearly all other causes of death combined.¹³ Because of the substantial strain that heart disease places on society, physicians, scientists and policy makers have, for decades, devoted significant amounts of time and resources to combating its effects. Furthermore, numerous health organizations have undertaken efforts to better educate the public about demonstrable linkages between heart disease and personal choices regarding diet and lifestyle.¹⁴ Despite these efforts, however, a large segment of the population lives with hearts that have been severely damaged by heart disease, and thus face imminent death. For such patients, the traditional course of action has been allotransplantation, namely, a transplant process involving a human donor heart.¹⁵ This technique has undergone myriad improvements over the past several decades, and the health outcomes now associated with it are remarkably positive, at least in the near term. Indeed, “the 85% immediate survivors, 65% five-year survivors and the 40% ten-year survivors generally have good functional capacity.”¹⁶ The virtues of allotransplantation, however, are necessarily limited by the inherent scarcity of donor hearts. The market for donor hearts is one area in which demand has always outpaced supply. Each year, about 30,000

¹¹Id.

¹²Robert J. Lefkowitz and James T. Willerson, “Prospects for Cardiovascular Research”, *Journal of the American Medical Association*, Vol. 285 No. 5, (February 7, 2001), available at <http://jama.ama-assn.org/issues/v285n5/full/jsc00362.html> (March 3, 2001)

¹³See O.H. Frazier, MD, John M. Fuqua, Jr., and David N. Helman, MD, *Clinical Left Heart Assist Devices: A Historical Perspective*, in Daniel J. Goldstein, MD and Mehmet C. Oz, MD, Cardiac Assist Devices, Futura Publishing Company, Inc., Armonk, NY (2000), p.3

¹⁴See *Understanding Heart Failure*, *supra* note 9, at 2

¹⁵See *Expert Panel Review of the NHLBI Total Artificial Heart Program, June 1998-November 1999*, Vallee Willman (chair), available at <http://www.nhlbi.nih.gov/resources/docs/tah-rpt.htm> (April 6, 2001), p. 14

¹⁶Id.

patients are deemed eligible candidates for heart transplantation.¹⁷ However, only a small fraction of this group, numbering about 2000, actually winds up receiving donor hearts.¹⁸ Given the current figures, it is unlikely that the supply of donor hearts will increase enough to render allotransplantation a viable means of combating end-stage heart disease on a macro level.

Artificial heart technology represents society's most promising attempt at filling the above void. This technology has two main branches. Partial devices supplement patients' natural heart function, assisting those patients whose organs, while somewhat viable, are incapable of functioning adequately on their own. Total artificial hearts (TAH), on the other hand, are devices that actually replace patients' natural hearts. Such devices are designed for situations in which natural organs are so damaged that even supplementation via a partial device isn't enough to produce sufficient circulatory function. Collectively, partial and total artificial heart devices are classified as mechanical circulatory support systems (MCSS). Surgeons employing these devices face the unenviable challenge of outwitting the human body. Although it is relatively easy to slip pumps inside the body, it is difficult to do so in a manner that prevents the body from discovering this intrusion and ultimately rejecting the devices.¹⁹

MCSS technology has the capacity to benefit patients in three primary ways. First, devices can serve as "bridges" to transplant, allowing patients' conditions to stabilize while they await the delivery of donor hearts. Second, partial devices can be used, either temporarily or permanently, to allow a patient's natural heart to rest and recover following periods of distress. Finally, TAH devices can potentially serve as permanent replacements for those patients whose natural hearts are too damaged to permit recovery through alternative means. Replacement TAH devices represent the cutting edge of technology in this field. While their composition must accommodate a seemingly infinite number of scientific constraints, researchers are

¹⁷See Zina Moukheiber, *Lonely Heart*, FORBES MAGAZINE (April 17, 2000), available at www.forbes.com/forbes/2000/0417/6509430a.html (April 6, 2001)

¹⁸Id.

¹⁹See Transcript of NOVA #2617: "Electric Heart" (PBS Air date December 21, 1999), available at <http://www.pbs.org/wgbh/nova/transcripts/2617eheart.html> (March 7, 2001)

optimistic about their potential benefits. According to some observers, as these devices begin to improve in terms of their longevity and reliability, their success rates will begin to approximate those of the current “gold standard,” namely allotransplantation, and may ultimately even exceed them.²⁰ Advances in the area of artificial heart technology are particularly important at a time when non-surgical treatment methods for heart disease are deemed palliative at best, and are characterized by high mortality rates and uncertainty.²¹ Indeed, some experts estimate that nearly half of the yearly deaths attributable to heart disease might be postponed through the use of MCSS.²²

Artificial heart technology is subject to FDA regulation under the Federal Food, Drug, and Cosmetic Act of 1938 (“Act”). The Medical Device Amendments of 1976 (“Amendments”) to the Act establish three regulatory classes for medical devices, “based on the degree of control necessary to assure that the various types of devices are safe and effective.”²³ Artificial heart devices are considered part of Class III, and are thus subject to the heaviest possible regulation. A Class III device is defined in the Amendments as “one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.”²⁴ Class III medical devices may not be marketed by firms until the FDA has approved a pre-market approval (PMA) application under Section 515 of the Act.²⁵ This statute, along with relevant FDA regulations, permits investigational uses of unapproved medical devices in certain situations. Such uses are allowed for the purpose of garnering the safety and effectiveness data necessary to support a firm’s PMA application. However, investigational uses, in the form of clinical trials, are only permissible once FDA has approved a firm’s application for an Investigational Device Exemption

²⁰See *The Artificial Heart: Prototypes, Policies, and Patients*, Committee to Evaluate the Artificial Heart Program of the National Heart, Lung, and Blood Institute, Division of Health Care Services, Institute of Medicine, John R. Hogness and Malin VanAntwerp (Eds.), National Academy Press (Washington D.C 1991), p.4

²¹*Id.*, at 35

²²*Id.*, at 16

²³See *Information on Premarket Approval Applications*, at <http://www.fda.gov/cdrh/pmapage.html> (April 18, 2001)

²⁴*Id.*

²⁵Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law*, 2d ed, The Foundation Press, Inc. (Westbury, NY 1991), p. 756

(IDE). IDE's are authorized under Section 520(g) of the Act. The function of an IDE application is two-fold. First, the application specifies the nature, purpose, and justification of the human clinical study proposed by a firm.²⁶ Second, the application presents substantial data that describes the device's mechanical design and its functioning during proper operation, while indicating a likelihood of successful clinical trials through reference to test-results from the pre-clinical stages of development.²⁷

When the regulatory system is functioning properly, the IDE and PMA approval processes arguably protect the market by weeding out devices deemed unsafe for society. However, "while the IDE system appears to have worked well for routine long term investigations of new devices... it seems less well-suited to studies of devices that are deployed infrequently but usually in an emergency setting."²⁸ Recognizing that emergency scenarios may arise in which uses of unapproved medical devices represent the best hopes for patients, the IDE regulation, 21 C.F.R. 812.35(a), "permits deviations from the investigational plan when necessary to protect the life or physical well-being of a subject in an emergency."²⁹ Further advice regarding emergency use is supplied in a related FDA guidance document.³⁰ The document suggests that a physician's use of an unapproved medical device, namely one that has received neither PMA nor IDE approval, will not spawn a negative response from FDA if such use is justified on the basis of an "emergency". An "emergency", as defined in the document, requires satisfaction of the following three pronged test:

- 1.

²⁶"Abiomed Requests FDA Approval to Begin Human Trials of AbioCor Replacement Heart", December 22, 2000, at <http://www.abiomed.com/about/press/122200.html> (February 23, 2001)

²⁷Id.

²⁸see Food and Drug Law, *supra* note 25, at 757

²⁹"Guidance on IDE Policies and Procedures", at <http://www.fda.gov/cdrh/ode/Idepolcy.html> (April 18, 2001)

³⁰"Guidance for the Emergency Use of Unapproved Medical Devices; Availability", 50 Federal Register 42866 (October 25, 1985), in Food and Drug Law, *supra* note 25, p. 759

2.

3.

Although the emergency use exception provides only a limited window in which to test artificial heart technology, it has nonetheless equipped some physicians with the ammunition necessary to deal with patients in particularly dire situations. Furthermore, clinical experiences with such patients have provided important lessons for surgeons and scientists hoping to one day gain approval for their projects through the formal regulatory process.

This paper tracks the historical evolution of artificial heart technology, from its humble beginnings, to its relatively staggering current potential. While examining various milestones along this fascinating timeline, the paper attempts to shed light on some of the ethical, economic, and social dilemmas that have infused this history. In doing so, it strives to provide the reader with a sense of the various factors, some technical in nature and others purely societal, that have wielded influence on this evolutionary process.

In conclusion, the paper proposes lessons for the future that can be gleaned from the experiences of heart researchers over the past several decades, and briefly assesses the impact that the development and proliferation of artificial heart technology will ultimately have on our nation's health care system.

Early History of TAH Devices

The development of total artificial heart technology can be traced to the early 1960's. At that time, most physicians in the field of heart surgery "had only begun to learn how to stop the heart, repair and start it again."³² However, Dr. Michael E. DeBakey had grander ambitions. DeBakey, a prominent surgeon at the Baylor College of Medicine in Houston, was a colorful and volatile figure known in medical circles as the "Texas Tornado" because of the admiration and fear he inspired in his colleagues.³³ His research interests led him to form a team whose purpose was to explore the feasibility of building an artificial device that could replace the natural human heart. DeBakey and his team were initially optimistic about the prospects for producing a well functioning device due to the relatively crude science that underlies the heart's pumping action. In his words, "We were thinking of the heart as just a pump, and it seemed logical that if that's the main function, you ought to be able to duplicate that mechanically."³⁴

DeBakey displayed this unfailing optimism while proposing a federal program to aid in the development of artificial heart technology during a 1963 congressional hearing. At this hearing, DeBakey asserted,

Experimentally, it is possible to completely replace the heart with an artificial heart, and animals have been known to survive as long as 36 hours. This idea, I am sure, could be reached to full fruition if we had more funds to support work, particularly in the bioengineering area.³⁵

The optimism of DeBakey and others in the field of heart surgery wielded considerable influence on lawmakers charged with the task of allocating funds to related research. This influence was augmented by the fact that the general population was beginning to experience "sky-high levels of heart disease."³⁶ Indeed, by 1965, a federal artificial heart program had been created, and its enabling legislation asserted that the program's

³² *Controversies from the Heart: Quest for Artificial Device Has Been Full of Contention, Drama*, Ruth SoRelle, HOUSTON CHRONICLE, (October 11, 1997), available at <http://www.chron.com/content/chronicle/metropolitan/heart/heart-history.3-0.html> (March 3, 2001)

³³ see Transcript, *supra* note 19

³⁴ *Id.*

³⁶ "PBS- Scientific American Frontiers: Affairs of the Heart: Searching for a Substitute," at <http://www.pbs.org/saf/1104/features/substitute2.htm> (February 21, 2001)

formation had been undertaken “with a sense of urgency.”³⁷ Under this program, 40 million dollars of funding was allocated towards heart research over four years, with human implantation tentatively slated to begin in 1970.³⁸

However, not all the principal players in this area shared the same values and priorities. Indeed, Dr. James Shannon, then head of the National Institutes of Health, believed that the excitement over artificial hearts was premature given the state of existing technology. Thus, he directed half of the funding received under the federal program to alternative forms of heart research, effectively stunting the pace and progress of efforts geared towards the development of artificial hearts.³⁹

Despite these constraining factors, some members of Dr. DeBakey’s research team in Houston were intent on pushing forward with the development of a total artificial heart. In the late 1960’s Dr. Domingo Liotta, one of the team’s principal researchers, approached DeBakey about the possibility of utilizing an artificial pump within human clinical trials. DeBakey was categorically opposed to the suggestion due to the limited level of success achieved during experiments conducted on animals. Today, DeBakey notes, “I explained to [Liotta] that we couldn’t do that because [the pump] had been used in seven calves, four of which had died on the operating table. We couldn’t go and get approval from our committee.”⁴⁰

Undaunted by DeBakey’s unwillingness to proceed, Liotta approached Dr. Denton Cooley, a protégé and colleague of DeBakey, and a surgeon at the nearby Texas Heart Institute.⁴¹ After meeting with Liotta, Cooley became convinced that a human trial of an artificial heart device was in fact an appropriate course of action. He felt that DeBakey’s refusal to take the next big step in artificial heart research indicated an overall lack of interest in the project. Liotta, on the other hand, feared that the countless hours he had

³⁷see *Controversies*, *supra* note 32

³⁸*Id.*

³⁹*Id.*

⁴⁰see Transcript, *supra* note 19

⁴¹*Id.*

spent toiling away in research labs and experimenting on animals would ultimately go to waste if the pump did not undergo the litmus test of a human trial. In the words of Cooley, “I thought, and agreed with Dr. Liotta, the time had come to really give [the pump] a test, and the only real test would be to apply it to a dying patient.”⁴²

Cooley and Liotta decided to proceed surreptitiously with their plan to utilize an artificial pump in a human patient. They would seek approval for their slated experiment from neither their internal committees nor external governing bodies such as the FDA. Today, while acknowledging that such approval probably would have been withheld, Cooley notes that “in those days, I didn’t feel like we needed permission,” other than the patient’s consent.⁴³

The visions of Cooley and Liotta came to fruition on April 4, 1969. That day, Cooley implanted an artificial heart into the chest cavity of 47 year old Haskell Karp of Skokie, Illinois, a printing estimator with a long history of heart related problems.⁴⁴ The “Liotta” device utilized in the operation had two chambers, and functioned in much the same fashion as a natural human heart, with one significant exception: “it was powered by enormous air pumps outside of the body, using hoses to pass through the patient’s body wall and into the circulatory system.”⁴⁵

Karp relied on the artificial device for more than two and a half days as he awaited the delivery of a human donor organ. However, shortly after receiving a human heart transplant at the Texas Heart Institute, Haskell Karp died of infection and related complications.

The Karp research episode was filled with controversy from top to bottom. First, the device to which Karp had been tethered while awaiting transplant had created a truly horrifying visual display. This disturbing

⁴²Id.

⁴³Id.

⁴⁴“A Who’s Who of Heart Recipients”, HOUSTON CHRONICLE, at <http://www.chron.com/content/chronicle/metropolitan/heart/patients.htm> (March 10, 2001)

⁴⁵see “Affairs of the Heart”, *supra* note 36

spectacle was described by the widow of Haskell Karp during an interview she gave to the BBC:

I saw an apparatus going into the arms, the hands, the feet. He could not say anything. I don't think that he was really conscious. I see him lying there breathing, and knowing that within his chest is a man-made implement where there should be a God-given heart.⁴⁶

This description embodies several of the principal criticisms that were levied against the Karp experiment shortly after it was commenced. Clearly, the device utilized was bulky and unwieldy, and given the fact that the patient was incapable of communicating with the outside world while attached to the artificial heart, many began to question the merits of research in this area.

Further controversy arose when Dr. DeBakey publicly acknowledged that the heart utilized by Dr. Cooley in his treatment of Karp was identical to a device that was under development in DeBakey's labs at Baylor. DeBakey further asserted that Cooley had used the device without his permission. Cooley then countered with the assertion that he and Dr. Liotta had actually developed the heart privately.⁴⁷ This controversy ultimately served to destroy the relationship between DeBakey and his protégé Cooley. Thus, Cooley and Liotta left Baylor to undertake the quest for the "holy grail"⁴⁸ of the successfully functioning artificial heart on their own. For her part, Karp's widow filed suit against Dr. Cooley, "alleging that she and her husband had been inadequately informed about the experimental nature of the artificial heart."⁴⁹ The suit, however, was ultimately dismissed by a federal court judge.⁵⁰

In essence, the Karp episode indicated that the initial optimism regarding the development of a functional artificial heart had been naïve.⁵¹ The scientific constraints involved were significant, and many years of effort would be required to overcome them, if such a result was even possible at all. Indeed, by 1971, Dr. DeBakey himself became convinced that existing total artificial heart technology could not overcome the

⁴⁷see *Controversies*, *supra* note 32

⁴⁸see "Affairs of the Heart", *supra* note 36

⁴⁹see "Who's Who", *supra* note 44

⁵⁰*Id.*

⁵¹see *Controversies*, *supra* note 32

hurdles intrinsic within the human body. DeBakey was primarily concerned with two major problems.⁵² First, scientists had to develop a power source that could be totally implantable, in order to reduce the risk of infection that was created by tethering artificial devices to external sources through skin penetrating pumps. Second, researchers had to discover and refine a non-clotting surface for the parts of the pump that actually came into contact with blood. Otherwise, the associated risk of stroke in patients would remain too high to warrant use of the technology. DeBakey ultimately determined that his time was better spent pursuing alternative avenues of heart research, asserting “I decided to stop putting my energies and efforts into a total artificial heart.”⁵³

Cooley, on the other hand, was disappointed in a different vein. While he acknowledged the scientific complexity of the initial experiment he had undertaken, he believed that focusing the public’s attention on the technology’s future potential would have a positive effect on the field of research as a whole. Even during the experiment, Cooley had asserted that “even if Mr. Karp goes nothing- doesn’t go any more than another day, I think that we have demonstrated that there is validity to this concept.”⁵⁴ However, Cooley had grossly miscalculated in the realm of public opinion. Confronted with the gruesome images of a suffering human patient, society at large began to regard the entire field of artificial heart technology as “more monstrous than miraculous,” and research efforts in this area were quelled to a substantial degree.⁵⁵ Cooley, now known affectionately as “The Man with the Golden Hands”, recently reflected on the outpouring of public sentiment in response to the Karp episode. He asserted, “I had hoped it (the Karp implant) would stimulate a flurry of interest in implants. People were discouraged because Haskell Karp didn’t live. If he had lived six months, it might have been different.”⁵⁶ Despite Cooley’s hopes, however, the development of total artificial heart

⁵²Id.

⁵³Id.

⁵⁴see Transcript, *supra* note 19

⁵⁵see “Affairs of the Heart”, *supra* note 36

⁵⁶see *Controversies*, *supra* note 32

technology, in response to the relative failure of the Karp experiment, stunted for more than a decade.

In the early 1980's a new figure named Dr. Robert Jarvik embarked on the quest for a well-functioning total artificial heart.⁵⁷ Jarvik had originally planned on pursuing a career as an architect or an engineer. However, his father's premature death as a result of heart disease pointed him in the direction of cardiac medicine.⁵⁸ Jarvik's passion for both the constructive and physical sciences made him an ideal candidate in the race to develop an artificial heart. Indeed, by 1982, Dr. Jarvik had begun conducting animal trials at the University of Utah with a device that he named the "Jarvik-7".⁵⁹ The Jarvik-7 was a total heart that completely replaced the natural organ within the body's chest cavity. Designed to function in a manner that parallels the human heart, the Jarvik-7 has two ventricle-like pumps, each having a disk-shaped mechanism that pushes blood from the inlet valve to the outlet valve.⁶⁰ The Jarvik-7's pumping action mirrors that of the natural heart, with one primary distinction: "the natural heart is living muscle while the artificial heart is plastic, aluminum, and Dacron polyester. As a result, the artificial heart needs some external source of 'life'."⁶¹ The device's "life", as such, is supplied by an external powering system that energizes and regulates pumping action through a system of compressed air hoses that enter the heart through the chest.⁶² Thus, the Jarvik-7 is inherently cumbersome and prone to the risk of infection.⁶³

In the early 1980's, Jarvik's team was one of five predominant groups working in the area of artificial heart research, and they had in fact achieved some degree of success during the initial phases of their work. Nevertheless, given the state of the economy, and the aversion towards this area of research held by many members of society, the Jarvik team was strapped for much needed funding. As medical historian Thomas Preston notes, "Here was a whole section of the university that had done a lot of work, good work, to get

⁵⁷see Transcript, *supra* note 19

⁵⁸*Id.*

⁵⁹*Id.*

⁶⁰ *The Franklin Institute Online: Building a Better Heart*, at <http://sin.fi.edu/biosci/healthy/fake.html> (March 10, 2001)

⁶¹*Id.*

⁶²*Id.*

⁶³*Id.*

to this point, and they were in danger of losing their financing. And they knew that they needed something big.”⁶⁴

Nothing, of course, was “bigger” than an attempt at rekindling the flames of human implantation. However, regulatory approval of such implantation would be almost impossible to obtain for obvious reasons. First, the device being utilized was, on a fundamental level, quite similar to the device that had been employed during the Haskell Karp episode of 1969. In the words of Dr. Cooley, “it was an almost identical heart based on the same principle.”⁶⁵ The notoriety of the Karp experiment militated against directly requesting regulatory permission to experiment with a device having reminiscent qualities.

Nevertheless, Jarvik and his colleagues were left with an end-run around the normal process of regulatory approval. As noted in the introduction to this paper, if implantation of the Jarvik-7 for particular patients was characterized as “necessary, life saving therapy”, then such uses would be somewhat immune to regulatory scrutiny. Such a characterization could be achieved if the patients selected were so ill as to be considered ineligible for human transplantation. This tiny window of opportunity for “borderline” research practices has always been a source of controversy within the medical and patient communities. As Preston observes about the Jarvik plan,

It’s interesting and important that the team called it ‘necessary therapy’. If they had said ‘Well, we don’t know how long he’ll live, then it would have been in the realm of experimentation, and it wouldn’t have been approved.’⁶⁶

Interestingly, FDA ultimately approved an IDE for the Jarvik-7 heart; however, the approval contained stringent protocol conditions that embodied the above factors.⁶⁷ After obtaining approval for the above form of transplantation, Jarvik approached Dr. DeBakey to request help with the testing of the Jarvik-7.⁶⁸ He proposed that five of the hearts be implanted at the University of Utah, and that another five transplants be

⁶⁴see Transcript, *supra* note 19

⁶⁵see *Controversies*, *supra* note 32

⁶⁷see *Food and Drug Law*, *supra* note 25, at 757

⁶⁸see *Controversies*, *supra* note 32

undertaken at Methodist Hospital in Houston. DeBakey was steadfastly opposed to the notion. Like many, he believed that the Jarvik-7 was hardly different from the Baylor heart used in the Karp case. Furthermore, he felt that research data that might support another such transplant attempt was simply unavailing.

Although he was spurned by the “Texas Tornado”, Jarvik found a comrade in Dr. William DeVries, a Utah surgeon who agreed to perform the device implants. The next hurdle, however, was finding patients that would be willing to subject themselves to the rigorous and frightening endeavor represented by artificial heart transplantation. Indeed, only patients who were truly on their last legs would be willing to undergo such operations.

DeVries and Jarvik found such a patient in Barney Clark. Clark, a 61-year old Seattle dentist, was quickly deteriorating from the effects of heart failure, and his physicians believed that his death was imminent.⁶⁹ Initially, however, even Clark was apprehensive about obtaining a Jarvik-7 transplant. Nevertheless, he decided to keep an open mind, and actually made a visit to the veterinary laboratory at the University of Utah in order to observe the calves that had received device transplants. Two days after this visit, Clark called Dr. Don Olson, a lead physician on the Jarvik research team, and asserted “The artificial heart is not for me.”⁷⁰

However, soon after making this declaration, Clark’s condition began to deteriorate further. He could now only sleep when propped up on pillows. Furthermore, a dying Clark had begun to appreciate the important role his transplant could play in terms of guiding future research efforts. In November of 1982, Clark notified Olson that he was now willing to undergo a transplant operation. “It may not work that well for me,” he said. “I’ll do it for the next patient.”⁷¹

On December 2, 1982, Barney Clark received a Jarvik-7 implant in Salt Lake City.⁷² From its earliest stages,

⁶⁹see “Who’s Who,” *supra* note 44

⁷⁰see *Controversies*, *supra* note 32

⁷¹*Id.*

⁷²see “Who’s Who”, *supra* note 44

the procedure turned out to be fraught with complications. It seemed that Clark was even sicker than his doctors had initially believed. By the time Dr Devries had opened Clark's chest and connected the patient to a heart-lung machine, Clark's natural heart was no longer functional, and had completely stopped on the operating table.⁷³

Clark was ultimately connected to the Jarvik-7, and managed to survive for 112 days while tethered to the device.⁷⁴ However, doctors associated with the operation acknowledge that each of these days was a struggle in some respect. For one, Clark's blood kept clotting as it flowed through the device, and these clots ultimately led to a number of strokes. Furthermore, some of the device's most important components were experiencing forms of mechanical malfunctioning. It soon became apparent that one of the critical valves within the device that had broken in Clark had never undergone stringent testing in the context of an artificial heart.⁷⁵ A series of operations was needed to repair elements characterized by Jarvik as the "weak links in the system."⁷⁶

In addition to the mechanical and medical complications involved in his transplant, Clark was forced to endure the difficult physical and emotional demands placed on him by the apparatus. The Jarvik-7's large size, approximately that of a washing machine, and the loud wheezing sounds emitted by its pumping of compressed air, were noticeable to all who witnessed Clark's progress, or lack thereof, first hand. Furthermore, the pulses of compressed air that powered the machine "jolted Clark with every beat."⁷⁷ Nevertheless, Clark's resolve appeared to strengthen over the course of his 112 day saga. During those limited moments when he had sufficient strength to discuss his condition with the media, he unequivocally expressed support for the procedure. At one point, Clark described his experience as "a pleasure to be able to help peo-

⁷³see *Controversies*, *supra* note 32

⁷⁴*Id.*

⁷⁵see Transcript, *supra* note 19

⁷⁶*Id.*

⁷⁷"Reviving Artificial Hearts", Michael D. Lemonick, *Time Magazine*, Saturday, March 3, 2001, available at <http://www.time.com/time/magazine/printout/0,8816,44039,00.html> (March 3, 2001)

ple. . . maybe you folks'll learn something.”⁷⁸ What made Clark’s contribution to the field so heroic was the fact that he never harbored any illusions about miracle outcomes. As Dr. Olson notes, “We considered him a true pioneer. [Clark] looked at it as one in a long series of experiments. He knew that he would die on the device.”⁷⁹

Clark’s courageous adventure with the Jarvik-7 was a hotly pursued story for the national news media, which tracked the patient’s progress on a continuous basis. As Jarvik reflects, “There was this human drama that was almost like, like a serial, almost like a soap opera: what’s going to happen tomorrow?”⁸⁰ This “human drama” slowly evolved from a profile in courage to a real life horror show. With regard to public perceptions, the very source of the Clark transplant’s notoriety turned out to be its undoing. Jarvik’s team had touted their device as a form of “destination” therapy. Unlike the artificial heart utilized by Haskell Karp as a “bridge” to transplant, Clark’s Jarvik-7 was intended to stay inside his body for the rest of his life. As Jarvik asserts, “That intention, symbolically, is part of the thing that brought so much attention to the Barney Clark case.”⁸¹ However, this intention was also what made the Clark case so problematic. To the lay observer, strapping patients to bulky and noisy contraptions for life was degrading and cruel, despite Clark’s heroic protestations to the contrary. The fact that the device didn’t even work well was simply the final straw.

After Clark’s death, the Jarvik-7 was implanted in a second patient, 53 year-old William Schroeder, at the Humana Heart Institute in Louisville, Kentucky.⁸² Schroeder actually survived on the device for 18 months. Like Clark, however, Schroeder was plagued by multiple strokes, infections, and hemorrhages throughout the

⁷⁸see Transcript, *supra* note 19

⁷⁹see *Controversies*, *supra* note 32

⁸⁰see Transcript, *supra* note 19

⁸¹*Id.*

⁸²see “Who’s Who”, *supra* note 44

course of his treatment.⁸³ Unlike Clark, however, Schroeder was candid about the physical ordeal created by the device. Schroeder's painful struggle was witnessed first hand by Boston University ethicist George Annas, who described the patient as existing in a twilight state "between being alive and dead."⁸⁴ When asked directly for his opinion about the Jarvik-7, Schroeder "made a horrible gesture, like he'd like to kill it or strangle it."⁸⁵ After Schroeder's death, public sentiment against artificial heart research reached alarming levels. In response, FDA effectively revoked the IDE granted to the Jarvik-7 program. An FDA advisory committee reviewing the program noted, "FDA should assume a more direct oversight role as the clinical trial proceeds, and should approve subsequent implants on a case by case basis."⁸⁶

Despite the courageous sacrifices made by Clark and Schroeder, the high profile failures of the Jarvik implants had stifled rather than stimulated research in the area of total artificial heart technology. As Preston notes, "The value that we got out of that experiment, and that's all it was, was that it was not fit to be used at that time."⁸⁷ Most researchers now became convinced, as DeBakey had a decade earlier, that the quest for an effective total artificial heart was simply a fruitless endeavor. Furthermore, for those who emerged from the Jarvik implants with a more optimistic outlook, continued efforts in this area would encounter heated resistance from both regulatory bodies and the public at large. As a result of these forces, researchers and surgeons now began to bolster their efforts at finding alternative ways to combat heart disease.

Heart Assist Devices

⁸³"Artificial Hearts Pumping Ahead", Steve Sternberg, *USA Today*, October 23, 2000, available at <http://www.usatoday.com/life/health/heart/lhhea150.htm> (March 10, 2001)

⁸⁴*Id.*

⁸⁵*Id.*

⁸⁶See *Food and Drug Law*, *supra* note 25, at 757

⁸⁷See Transcript, *supra* note 19

Discouraged by the relative failure of TAH implants in patients like Barney Clark, and society's growing apprehensiveness towards the very idea of such devices, leaders in the field of heart research began to focus their energies on the development of technologies that were less daunting. One such technology involved the use of simpler "partial" pumps that could assist or supplement the heart's function as it recovered from surgery. However, while the 1980's witnessed a resurgence in this particular area of research, the development of heart assist devices can actually be traced to the very beginnings of artificial heart technology.

The commencement of the modern era of mechanical circulatory support occurred in the early 1950's with the work of John H. Gibbon Jr.⁸⁸ In 1953, Gibbon became the first surgeon to successfully utilize a cardiopulmonary bypass (CPB) in a clinical setting.⁸⁹ The virtue of the CPB, or "heart-lung" machine, was that it provided a quiet and bloodless field for physicians performing open-heart surgery. Essentially, the heart would be temporarily stopped while surgeons operated on the organ. During this period of stoppage, the CPB machine would take over the circulatory functions normally performed by the natural heart and lungs. After the surgical procedure was completed, the patient would be gradually removed from the CPB machine, and normal heart function would be restored.

As surgeons became more adept at performing these procedures, they began to realize that certain heart patients needed one to two hours of additional cardiac support before they could be successfully removed, or "weaned", from CPB machines.⁹⁰ Those patients that could not be weaned would die without ever experiencing the benefits afforded by the surgical procedures they had undertaken.

Since pulmonary function was usually adequate in patients utilizing CPB devices, surgeons began to believe that a more prolonged form of cardiac support was needed.⁹¹ While the CPB machine was equipped to

⁸⁸JH Gibbon Jr. "Application of a Mechanical Heart and Lung Apparatus in Cardiac Surgery." *Minn Med* 1954;37:171-185

⁸⁹see *Clinical Left Heart Assist Devices: A Historical Perspective*, *supra* note 13, p.3

⁹⁰*Id.*

⁹¹*Id.*

provide valuable short-term cardiac support, its use was often a source of damage to end organ function and to other formed blood elements.⁹² Furthermore, the mechanical constraints inherent within the CPB machine implied that the device had a built-in time limit of four to six hours. Essentially, heart surgeons longed for a less physiologically damaging and longer-term device that would allow the heart to rest long enough for its intrinsic reparative processes to occur.⁹³

Since the lion's share of the work performed by the heart is attributable to the left ventricle, some researchers began to search for ways to eliminate left ventricular failure in patients recovering from heart surgery. One such researcher, C.W. Hall, developed a left ventricular bypass pump.⁹⁴ Constructed from a Dacron reinforced silicone rubber material, this implantable left ventricular assist device (LVAD) could theoretically take over part of the natural organ's functional role, allowing it to heal following the trauma and distress of a surgical operation. The device achieved successful results during a series of animal trials.⁹⁵ Then, on July 18, 1963 the LVAD was implanted in a human patient who had developed cardiogenic shock after undergoing an aortic valve replacement.⁹⁶ Although the pump appeared to function in a satisfactory way, the patient in whom the device had been implanted had suffered a serious neurologic injury prior to implantation. Despite the adequate circulatory support provided by the LVAD, this injury failed to improve. Thus, use of the LVAD was discontinued after just 4 days.⁹⁷

In 1966, a more refined version of the pump, named after its creator Dr. DeBakey, was implanted in a patient following double valve replacement surgery.⁹⁸ This device, which was placed extracorporeally, could be removed without actually opening the chest. The patient was supported by this LVAD for ten days

⁹²Id., at 4

⁹³Liotta D, Hall CW, Henly WS, et. al. "Prolonged Assisted Circulation During and After Cardiac or Aortic Surgery", *Am J Cardiol* 1963;12:399-405

⁹⁴Hall CW, Liotta D, Henly WS, et. al. "Development of Artificial Intrathoracic Circulatory Pumps", *Am J Surg* 1964;108:685-692

⁹⁵see *Clinical Left Heart Assist Devices: A Historical Perspective*, *supra* note 13, p.4

⁹⁶Id.

⁹⁷Id.

⁹⁸DeBakey ME. "Left Ventricular Bypass Pump for Cardiac Assistance: Clinical Experience", *Am J Cardiol* 1971;27:3-11

as his heart recovered from the turmoil of surgery. Ultimately, he survived and was discharged from the hospital, marking the first occasion in which an LVAD had been successfully utilized for the treatment of postcardiotomy heart failure.⁹⁹

In the years following this episode, researchers became more adept at utilizing LVAD type devices in patients post-surgery, and refined versions began to proliferate. Furthermore, a growing consensus was emerging as to the generally positive results associated with LVAD implantation. A Texas Heart Institute study, for example, concluded that LVAD use “could reduce all indices of myocardial work yet increase systemic perfusion and coronary blood flow.”¹⁰⁰ Optimistic results such as these convinced some researchers that LVAD devices could be utilized as “bridges” to transplant for patients awaiting donor organs, in the way that researchers had previously attempted to employ total artificial heart devices. The first such use of the LVAD occurred in 1978, when a 23-year old patient undergoing double-valve replacement fell victim to irreversible stone heart failure post-operatively.¹⁰¹ The patient was supported by an LVAD device for seven days as he awaited the receipt of a donor organ. A second patient received an artificial heart implant as a “bridge to transplant” in 1981 at the Texas Heart Institute.¹⁰² While the devices utilized as bridges performed relatively well in both of these patients, each ultimately died of infectious complications after receiving a donor heart. These complications were rooted in the aggressive use of immunosuppressant drugs by the patients. Such use was required in order to avoid the body’s rejection of the implanted donor organs. The risk of such use, however, was that it effectively disabled the body’s natural immune system. This disablement was coupled with the fact that the patients taking the drugs were already plagued by an extremely high risk of infection “as a result of general contamination from the procedures needed to implant the circulatory support devices.”¹⁰³ Thus, despite their successful functioning, the infectious risks that accompanied the implantation and re-

⁹⁹see *Clinical Left Heart Assist Devices: A Historical Perspective*, *supra* note 13, p.5

¹⁰⁰*Id.*, at 6

¹⁰¹*Id.*, at 7

¹⁰²*Id.*

¹⁰³*Id.*

moval of LVAD's initially rendered them an untenable means of stabilizing the condition of patients who were awaiting the receipt of donor hearts.

In the early 1980's, researchers attempting to utilize LVAD technology to bridge patients to transplant received a fortuitous jump-start. Scientists at Sandoz Pharmaceutical Corporation in New Jersey discovered and developed cyclosporine, an immunosuppressant whose results were far superior to those of previously marketed drugs.¹⁰⁴ The amazing results tied to cyclosporine spawned a resurgence in the field of heart transplantation, and many clinical centers that had discontinued their transplant programs began to accept patients once again. However, donor hearts remained quite scarce, and the problem of patients dying while on the waiting list for organs began to intensify. To combat this problem, several of the left ventricular assist systems that had been developed to provide long term support to patients were approved as investigational devices by the FDA to bridge patients to transplant.¹⁰⁵ The results of these trials proved remarkably successful. In 1985, Peer Portner and his colleagues at Stanford reported the first successful use of Baxter Healthcare Corporation's Novacor LVAD, an implantable electromagnetic device, as a bridge to transplantation.¹⁰⁶ At the Texas Heart Institute, several successful trials of various LVAD's as bridges to transplant followed. Included among these devices were several specialized pumps, geared at short and long-term uses respectively.

Researchers attempting to refine LVAD systems as bridges to transplant faced serious scientific obstacles. One of the most daunting challenges was designing a pump that didn't cause strokes within patients. The strokes that were occurring resulted from problems that inhered within the placement of synthetic devices inside the human body. As blood flowed through LVAD's, white blood cells would detect even the tiniest of imperfections or flaws contained on the inside surfaces of the pumps.¹⁰⁷ To combat the imperfections,

¹⁰⁴Id.

¹⁰⁵Id. p. 8

¹⁰⁶Portner PM, Oyer PE, McGregor CGA, et. al. "First Human Use of An Electrically Powered Implantable Ventricular Assist System", *Artif Organs* 1985;9:36.Abstract.

¹⁰⁷see Transcript, *supra* note 19

these cells would fill in the flaws in order to generate an entirely smooth surface. As a result of this filling in process, biological deposits would begin to form inside the pumps. The deposits weren't problems in and of themselves; however, if these "emboli" somehow managed to break free from the surfaces of pumps into the flowing blood stream, they could eventually become lodged in small vessels within the brain, cutting off perfusion and causing strokes within patients.

For years, scientists toiled away at refining the internal surfaces of their pumps. However, despite the improvements generated by them, the materials produced still fell short of the standard of perfection required by the human body. Essentially, white blood cells were equipped to identify even the most miniscule of flaws, and these flaws were present despite the most strenuous efforts of researchers.

Frustration with the traditional approach of refining pump surfaces led to a sea change in terms of research strategies. In the words of Dr. Mehmet Oz,

After years of trying to overpower Mother Nature, the tack was changed, and we said, 'Let's allow you to coat your blood cells over a very rough surface, a surface so rough that once your blood sticks to it, it can't come off again.'¹⁰⁸

Rather than undertaking the futile quest to develop a flawless surface, researchers now focused their energies on developing a strategically flawed surface, one that would actually encourage the formation of biological deposits, but at the same time prevent such deposits from ever breaking free into the blood stream and causing strokes. The strategy proved to be an ingenious one. Soon, the Heartmate pump, the only completely implantable device that actually employed the "rough surface" approach, began to dominate the market, as its low stroke rate achieved significant notoriety.¹⁰⁹ Equipped with this revamped technology, hospitals could now stabilize several patients for months or even years as they awaited the receipt of donor organs.

¹⁰⁹Id.

Another problem associated with LVAD technology was the extremely large size of the pumps. While large patients could feasibly employ implantable, battery-powered pumps, the only available options for smaller patients involved assist devices that remained outside their bodies. Since these patients needed to be attached to large external consoles, they were forced to remain bedridden while they awaited transplant.¹¹⁰

The large sizes of LVAD systems were rooted in the assumption that the pumps needed to be “pulsatile”, namely, that they needed to “beat” in a way that mimicked the pumping action of the natural heart. Human beings require a pulse in order to allow the natural heart to rest between beats, and absorb the energy that the heart requires to pump blood.¹¹¹ Recreating the pulse, while mechanically possible, greatly increased the necessary size of pumps, due to the substantial power required by this process.

In attempting to develop smaller pumps that could better accommodate the needs of patients without large body types, some scientists posited that while the natural heart needed time to rest between beats, a purely mechanical device constructed of artificial materials did not.¹¹² One such scientist, Dr. Richard Wampler, began to develop a non-pulsatile LVAD. Wampler was convinced that the body might not necessarily need a pulse to function effectively. This belief in “continuous flow” pumps was rooted in his observations of how blood actually functions within the human body. In his words,

It is true that if you go out into your arm, when you go to the doctor that you can feel your radial artery and you’ll feel a pulse, but when you go out on the capillary level, by that time, the pulsatility is totally damped, so really at that level the flow is continuous flow going through these capillaries.¹¹³

Armed with this insight, Wampler and his team developed a tiny axial flow pump that could provide short-term assistance to the heart. An axial flow pump functions by spinning an Archimedes screw; this screw draws fluid in at one end and sends it out the other.¹¹⁴ Through this pump, blood flows continuously without

¹¹⁰Id.

¹¹¹Id.

¹¹²Id.

¹¹⁴Id.

a pulse. Wampler's device was tested on animals for about two years. Then, in 1988, surgeon O.H. "Bud" Frazier implanted the device in a dying transplant patient.¹¹⁵ The results of this trial were remarkably positive. The pump actually allowed the patient's weakened heart to rest long enough to recover. Most importantly, this study showed that the nonpulsatile flow inherent within the device was well tolerated by mammalian circulation.¹¹⁶ As Frazier notes, "That was a very dramatic thing because it showed us that, number one, patients could live without a pulse."¹¹⁷ The optimism fostered by the initial trial of the Hemopump was bolstered by the successes achieved by implants within several other patients after 1988. Indeed, over 100 patients who could not utilize standard LVAD systems were saved by this technology.¹¹⁸ Frazier's experience with one young patient is particularly illustrative of the remarkable insights gained through use of this device:

I had one little boy that lived for about three days without a pulse at all. He was very small, and this small pump could take over his entire circulation. He woke up, he ate Popsicles and he did very well until his heart had recovered enough to start beating.¹¹⁹

The Hemopump had effectively overcome the traditional presumption against the viability of nonpulsatile LVAD's. Equipped with this new knowledge, researchers scrambled to create more refined instruments that embodied Wampler's basic concepts. One remaining problem associated with the Hemopump was its lack of power. Although the device could sustain a resting patient, it could only pump a small amount blood, far from what was needed to provide a patient with longer-term support. Furthermore, Wampler's pump could only be used temporarily, since it required a perpetual infusion of glucose to lubricate its moving parts.¹²⁰ Scientists feared that increasing the power of the screw pump, given its stringent lubrication needs, meant increasing the risk that blood flowing through the pump would be damaged during the process.

¹¹⁵Frazier, OH, Wampler RK, Duncan JM, et. al. "First Human Use of the Hemopump, a Catheter Mounted Ventricular Assist Device." *Ann Thorac Surg* 1990; 49:299-304

¹¹⁶see *Clinical Left Heart Assist Devices: A Historical Perspective*, *supra* note 13, p.9

¹¹⁷see Transcript, *supra* note 19

¹¹⁸*Id.*

¹²⁰*Id.*

In response, Robert Jarvik proposed that human blood itself could function as an effective lubricant for the pumps.¹²¹ Jarvik's challenge prompted many researchers to explore the possibility of a self-lubricating, continuous flow LVAD. Essentially,

the goal was to develop a permanent axial flow pump that was small enough to be implanted in the chest, but powerful enough to push blood through the thousands of miles of vessels in the body.¹²²

One of the researchers taking particular interest in this area was Dr. DeBakey. DeBakey had successfully performed a heart transplant on NASA engineer David Saussier. Out of both gratitude and curiosity, Saussier had become excited about the possible contributions that aerospace technology could make within the field of artificial heart research.¹²³ DeBakey, armed with Saussier's support, approached NASA about the possibility of creating an implantable, permanent, axial flow pump for use in LVAD's.

NASA was an ideal source of research support in the area of axial flow pumps. Indeed, the pumps of the space shuttle's main engines were themselves fueled by an axial flow motor system.¹²⁴ NASA agreed to collaborate with DeBakey in creating a permanent axial flow pump "at a fraction of the size of the current pulsatile devices."¹²⁵ Preliminary efforts produced a prototype device the size of a mere thumb.¹²⁶ When implanted inside the human body, it would create a powerful yet pulseless flow of blood. The device had just one moving component, known as the impeller.¹²⁷ The pump was powered through the use of magnets that were implanted inside the impeller blades. Essentially, a coil would create a magnetic field around the impeller, and as the field spun, it would drag the impeller with it. The use of magnetism to power the pump was an ingenious approach. Indeed, the pump could be spun at about 10,000 rpm, "drawing the blood in,

¹²¹Id.

¹²³Id.

¹²⁴Id.

¹²⁵Id.

¹²⁶Id.

¹²⁷Id.

propelling it out the back at about five liters per minute.”¹²⁸

However, the high-speed magnet driven pumps were not without their own set of pitfalls. Adding magnets into the equation necessarily affected the shape of the blades used to pump blood, and this created the risk that blood would somehow be damaged as it flowed through the pump. If such damage persisted, it would render use of the powerful device untenable. In the words of scientist Bob Benkowski,

The best analogy I can think of is pumping blood is like pumping a whole bunch of water balloons that are suspended in liquid. You’re trying to pump these water balloons without having them rupture.¹²⁹

To combat the problem of damaged blood, NASA scientists turned to the field of fluid dynamics. Using Cray super-computers, they electronically modeled the flow fields inside the pump’s impeller.¹³⁰ What they discovered was that even the tiniest of changes in the pump’s geometry, namely those approximating 10 or 20 thousandths of an inch in critical areas, would have a drastic effect on the overall viability of the pump.¹³¹ Effectively, the changes would create localized areas of high and low pressure within the pump.¹³² The resultant blood damage would then reach levels that were clinically unacceptable.

After several rounds of trial and error, DeBakey and the NASA scientists were able to achieve their ultimate goal, namely “designing magnetic blades which rotated so fast that blood cells weren’t damaged at all.”¹³³ Bud Frazier describes the phenomenon in more accessible terms: “It’s sort of like passing your finger through a candle... if it goes fast enough, then you don’t burn your finger.”¹³⁴

DeBakey’s device is now a business venture known as the MicroMed DeBakey VAD.¹³⁵ Silent, and weighing

¹²⁸Id.

¹³⁰Id.

¹³¹Id.

¹³²Id.

¹³³Id.

¹³⁴Id.

¹³⁵see “Innovation in Cardiovascular Therapy”, at <http://www.micromedtech.com> (April 4, 2001)

less than 4 ounces, the device has undergone clinical trials in Europe since the late 1990's. Having received IDE approval from FDA in the middle of 2000, DeBakey's team has been pursuing limited clinical trials at Methodist Hospital in Houston. Indeed, in January of this year, the FDA granted approval to expand this feasibility study to three sites and twenty patients.¹³⁶ Early results from both the European and American trials are promising, and DeBakey remains optimistic that his pump will one day achieve widespread acceptance within the health care system.

While DeBakey continued to perfect his miniaturized LVAD pump, Jarvik, working independently with a team in Manhattan, was hard at work developing his own axial flow pump. Appropriately named the Jarvik 2000, this pump is so small that it can actually be placed inside the human heart.¹³⁷ In fact, the pump is designed to be implanted inside the tip of the left ventricle.¹³⁸ Blood from the heart flows directly into the device, where it is pumped out to the various organs and tissues of the body. When it returns to the heart upon regeneration, the process essentially repeats itself. The only tube connected to the Jarvik 2000 is the outflow pump that exits the heart. Thus, by eliminating the inflow tube, Jarvik effectively removed a location where blood clots are likely to form.¹³⁹ Furthermore, unlike many pumps which require the conventional "opening of the chest" in order to achieve effective implantation, the Jarvik-2000 requires a less invasive incision on the left side of the chest.¹⁴⁰ Due to its relative ease of implantation, patients utilizing the device face shorter stints on heart-lung machines. Thus, their required periods of recovery post-transplant are also reduced.

¹³⁶see "Press Releases", at <http://www.micromedtech.com/micromednews.htm> (April 4, 2001)

¹³⁷see Transcript, *supra* note 19

¹³⁸*Id.*

¹³⁹*Id.*

¹⁴⁰"First Jarvik 2000 Clinical Trials Participant Receives New Heart" (July 20, 2000), at <http://www.texasheartinstitute.org/j2000700.html> (April 8, 2001)

Jarvik's team spent almost a decade refining his axial flow pump. In its final form, the device was the size of a "C" battery, and capable of pumping blood throughout the body at the rate of six liters per minute, near the top end of the range that characterizes the natural human heart.¹⁴¹ The pump itself is non-pulsatile, although the natural heart continues to beat and thus provides a pulse.¹⁴²

Early in the year 2000, Jarvik received FDA approval of an IDE to begin testing the Jarvik 2000 pump as a bridge to transplant at the Texas Heart Institute.¹⁴³ Then, on April 10, 2000, the device was implanted in a human being for the first time. The patient, Lois Spiller, was a 52 year old woman suffering from a form of cardiomyopathy that had led to an enlarged heart. Prior to receiving the pump, Spiller was bedridden and experiencing severe chest pain. Her experience using the Jarvik-2000 proved remarkably successful. Spiller survived on the pump for 79 days as she awaited the receipt of a donor heart. On June 28, 2000 the donor heart arrived, and was implanted within her by Frazier at St Luke's Hospital in Houston.¹⁴⁴ In Frazier's eyes, the series of procedures went exactly as planned. He asserted, "The heart-assist device performed extremely well and enabled [Spiller] to build up her strength before undergoing her transplant."¹⁴⁵ As of this paper's writing, Spiller's donor heart is performing well, and her condition continues to improve.

Three additional patients have received Jarvik 2000 transplants since Spiller's successful experiment, and although a couple of them continue to await the receipt of donor hearts, the assist device is performing quite well within them. In fact, in November of 2000, the FDA granted permission to Jarvik's team to extend the clinical trial of the device by five additional patients.¹⁴⁶ Although much remains to be seen with regard to the device's long-term outcomes, its short-term success within clinical trials bodes well for the field of heart assist technology. Jarvik views his informal competition with DeBakey in the development of tiny LVAD's as

¹⁴¹Id.

¹⁴²Id.

¹⁴³Id.

¹⁴⁴Id.

¹⁴⁵Id.

¹⁴⁶"Jarvik 2000 Clinical Trials Extended" (November 1, 2000), at <http://www.texasheartinstitute.org/j2001100.html> (April 8, 2001)

healthy for the field of medicine. Nevertheless, he acknowledges the fact that what really matters is success at the end stage of the game. In his words, “If you compare it to a prize fight, who throws the punch first is not so important as who’s there at the end and who throws the punch last.”¹⁴⁷

As LVAD technology has continued to improve over the past decade, doctors have begun to reconsider the goals that underlie these devices. As previously noted, LVAD’s were originally geared towards patients that were recovering from heart surgery. As time passed, researchers became optimistic about the possibility of utilizing LVAD’s as bridges to transplant for patients awaiting donor organs. However, a large percentage of patients awaiting donor organs were required to wait substantial periods of time between receipt of their LVAD’s and actual organ transplantation. This externally imposed waiting period allowed physicians to observe, through electronic imaging, the short-term effects of LVAD use on the natural hearts of patients. In some cases, what they found astonished them. One such case involved Norbert Hilbert, a German patient suffering from a viral infection in his heart.¹⁴⁸ In September of 1994, Hilbert was rushed to the Berlin Heart Institute as his condition began to worsen. X-rays showed that Hilbert’s heart was extremely enlarged. Berlin doctors implanted an LVAD device inside Hilbert, and he began the interminable wait for a donor organ. Nine months later, doctors noticed something out of the ordinary on Hilbert’s X-rays: his heart had shrunk back, and was now nearly its normal size. This shrinkage was attributable to the important supplementary function performed by Hilbert’s LVAD device. In the words of Dr. Stephen Westaby,

What happens when you put an LVAD into the left ventricle is that there is no longer pressure within that heart chamber, and completely rests the left ventricle. And what chronic rest does is allow the very much enlarged heart cells to go back to normal size. If you intervene early enough, you’ll get that heart failure process to reverse.¹⁴⁹

Rather than continuing the wait for a donor organ, Hilbert’s doctors allowed his heart to complete its process of recovery, and then removed the LVAD device for good. Years later, Hilbert’s heart was functioning as

¹⁴⁷see Transcript, *supra* note 19

¹⁴⁸*Id.*

well as ever.

Hilbert's case is illustrative of the monumental contemporary conception known as "bridge to recovery."¹⁵⁰ Essentially, certain patients whose hearts are severely damaged, but not irreparably so, are provided finite support from cardiac-assist devices. Once the process of rest and recovery has completed its course, the devices are removed, and patients utilize their natural hearts for the remainder of their lives. The "bridge to recovery" approach was borne of the time limitations inherent within the use of LVAD devices as bridges to transplantation. In heart disease patients utilizing the latter approach, doctors were able to compare myocardial tissue samples at the time of maximal heart failure, namely that of LVAD implantation, with samples taken from the heart at the time of transplantation, after the heart had received prolonged cardiac rest by virtue of the assist device.¹⁵¹ These comparisons revealed that for some patients, improvements generated by use of LVAD's rendered heart transplantation at the second stage unnecessary.

Although patients like Norbert Hilbert have demonstrated the feasibility of a bridge to recovery approach, doctors continue to struggle when it comes to identifying those patients for whom such an approach is practical. It remains the case that some patients have natural hearts that are too damaged to employ an LVAD-only approach. Nevertheless, as researchers become more adept at singling out patients in the bridge to recovery category, the overall demand for heart transplants may be reduced, which represents good news for patients on waiting lists, for whom allotransplantation remains the only hope. Recent developments indicate, however, that patients in this latter category may soon be granted access to a holy grail of their own.

¹⁵⁰see *Clinical Left Heart Assist Devices: A Historical Perspective*, *supra* note 13, p.11

¹⁵¹*Id.*

AbioCor Total Artificial Heart

Although the 1982 Barney Clark research episode was extremely informative in many regards, the experience in several ways served to chill efforts at developing total artificial heart technology. This chilling effect stemmed in large part from the negative public perceptions that accompanied Clark's pioneering experiment. When Clark was interviewed three months following his transplant, several disturbing facts came to the fore. Although Clark was in fact cognizant, the life-sustaining machine to which he was connected was both bulky and noisy, and Clark appeared to be visibly shaken by its life altering ancillary effects.¹⁵² Indeed, Thomas Preston asserts that after the operation, Clark's reliance on the cumbersome Jarvik-7 apparatus afforded what amounted to a "negative quality of life."¹⁵³ The extremely large amount of media coverage provided to the Clark operation proved to be a double-edged sword for researchers in this area. While the press' love affair with Clark's story initially focused public attention on the amazing potential benefits of heart research, the vivid and disturbing images of Clark's suffering after his operation shifted public opinion squarely in the opposite direction. Commentators who had once championed the efforts of ambitious heart surgeons now openly questioned whether it was appropriate for human physicians to be "playing God" in this area. Even those who chose not to oppose the technology on abstract moral grounds questioned whether the technology could ever be refined to a point where its health benefits would outweigh its value as a mere scientific or theoretical curiosity. Although the notion of a man eternally strapped to a noisy device the size of a laundry machine might be tolerable for forward looking physicians and researchers, the public at large viewed the concept as utterly inhumane and entirely unacceptable. As noted earlier in this paper, the changing tides of public perception led to significant changes in the priorities of researchers. Rather than continuing to toil

¹⁵²see Transcript, *supra* note 19

¹⁵³*Id.*

away in a field that now bore the label “The Dracula of Medical Technology”¹⁵⁴, most scientists shifted their focus toward partial and temporary devices that could aid in the recovery process of damaged hearts, and provide short run support for those patients likely to receive donor organs.

Despite popular perceptions, however, the Jarvik-7 device utilized in the Clark case was far from a categorical failure. After a brief hiatus following its failed use as a destination therapy, the Jarvik-7 was successfully utilized a number of times as a bridge to transplant for patients awaiting donor organs.¹⁵⁵ As doctors became more adept at using anticoagulant drugs to reduce the risk of stroke associated with these transplants, the success rate of the device continued to improve.¹⁵⁶ Indeed, since 1993, 147 patients have been supported by Jarvik’s original artificial heart, and 88 of these patients ultimately survived till their scheduled organ transplants.¹⁵⁷

Dr. David Lederman, unlike most of his peers and perhaps the rest of society, viewed the 1982 Clark experiment as a marked success. Rather than shifting gears squarely toward partial devices, Lederman maintained efforts at perfecting total artificial heart technology at his firm, Abiomed Inc, while attempting to remedy several of the obstacles that had been discovered during the Clark case. Based in Danvers, MA, Abiomed has focused its energies over the past decade on developing, manufacturing, and marketing products designed to assist or replace the failing heart.¹⁵⁸ Abiomed has attempted to infiltrate all areas of the “heart failure” market by providing a range of products designed to assist persons with varying degrees of life threatening or life impairing heart failure.¹⁵⁹ In doing so, it has established itself as a pioneer in the area of mechanical cardiac intervention, a field geared at improving and extending the lives of patients “whose needs have exceeded the limits of pharmaceutical therapies, cardiological intervention, and surgical

¹⁵⁴see “Reviving Artificial Hearts”, *supra* note 77

¹⁵⁵see “Artificial Hearts Pumping Ahead,” *supra* note 83

¹⁵⁶see Transcript, *supra* note 19

¹⁵⁷*Id.*

¹⁵⁸“About Abiomed”, at <http://www.abiomed.com/Fabout.html> (February 23, 2001)

¹⁵⁹*Id.*

correction.”¹⁶⁰ Although the company maintains significant involvement in all areas of the heart failure market, its attention is currently focused on the AbioCor Implantable Replacement Heart. This device is a fully implantable prosthetic system, intended as a destination therapy for patients whose natural hearts are severely damaged due to conditions involving coronary heart disease or some form of congestive end-stage heart failure.¹⁶¹ The AbioCor is premised on the notion that some patients have hearts that have suffered irreparable harm. For such patients, death is imminent unless a replacement can be found in short time. Due to the inherent shortage of human donor organs, however, many of these patients die before organs become available. The AbioCor is society’s most promising current attempt at saving patients in this category. The device itself is a technological and engineering marvel. Weighing a mere two pounds, AbioCor is a hybrid instrument composed of both titanium and plastic.¹⁶² The small size and light weight of AbioCor represent significant advances over prior attempts at creating total artificial hearts, as illustrated by the suffering of patients like Haskell Karp and Barney Clark. Unlike many of its various predecessors, AbioCor doesn’t necessarily require that patients utilizing the device have large physical builds or body types capable of handling the implantation of bulky instruments inside the abdomen. In fact, the AbioCor is approximately size of a grapefruit¹⁶³, a welcome fact for the women, children and smaller men that were effectively excluded by the constraints of prior technology.

AbioCor embodies several other improvements over prior efforts at creating total artificial hearts. After implantation, the device does not need to be tethered to external power sources by tubes or wires passing through the skin. Rather, AbioCor receives its much-needed power through “transcutaneous” transmission, a process that takes place across intact skin.¹⁶⁴ The fact that the device can function independent of wiring

¹⁶⁰Id.

¹⁶¹“Nearing Clinical Trials: AbioCor”, at <http://www.abiomed.com/prodtech/Fctrials.html> (February 23, 2001)

¹⁶²see Transcript, *supra* note 19

¹⁶³see “Nearing Clinical Trials”, *supra* note 161

¹⁶⁴“Artificial Heart Shows Promise”, Dr. Bob Arnot, (January 14, 2001), at <http://www.msnbc.com/news/355857.asp> (April 8, 2001)

and tubing that cuts through the skin provides a significant reduction in the risk of infection relative to that faced by patients utilizing older technologies. This risk was so serious that Dr. Mehmet Oz, one of the most highly respected contemporary cardiac surgeons, once labeled the percutaneous line the “Achilles heal” of artificial heart technology.¹⁶⁵

The AbioCor’s functional process is modeled after the process utilized by the natural human heart. In fact, AbioCor, like the human heart, actually consists of two blood pumping chambers. The “right” pump is charged with supplying blood to the patient’s lungs, while the “left” pump provides blood to other vital organs and to the rest of the body.¹⁶⁶ Each of the AbioCor’s pumps is capable of delivering more than two gallons of blood, or approximately eight liters, during every minute of its operation.¹⁶⁷ Despite this staggering physical capability, the device actually operates in relatively quiet fashion. Indeed, a stethoscope is required to listen to the “heart sounds” produced by the machine.¹⁶⁸

The process through which power is supplied to the AbioCor device is itself rather ingenious. AbioCor contains an internal controller that is embodied within the prosthetic implant.¹⁶⁹ This controller regulates the level of power that is supplied to the device based on its needs at any given moment in time. The device’s needs, in turn, are determined by the needs of the patient’s body. Indeed, the AbioCor system is designed to increase or decrease its pump rate in response to the body’s demands. These demands can shift during situations involving physical exertion and the like.

Without actually piercing the patient’s intact skin, an external controller transmits power to the AbioCor’s internal controller, in effect “recharging” it as its power supply begins to diminish with use. The internal controller is supplemented by another, smaller internal battery which is rechargeable as well. This supple-

¹⁶⁵see Transcript, *supra* note 19

¹⁶⁶see “Nearing Clinical Trials”, *supra* note 161

¹⁶⁷*Id.*

¹⁶⁸*Id.*

¹⁶⁹*Id.*

mentary battery allows the patient to be entirely free of the external power transmission unit for a certain period of time, while continuing to be monitored by AbioCor's internal system. The virtue of this back-up battery system is that it allows patients to perform certain daily tasks that would otherwise not be possible, such as taking showers and going for short swims.¹⁷⁰

Finally, the AbioCor contains a relatively sophisticated active monitoring system that is charged with providing detailed performance feedback. The system contains alarms that are triggered when patients experience forms of health irregularities that are tied to the device.¹⁷¹

Over the past several years, Abiomed engineers and physicians have been working diligently on refining the AbioCor in order to obtain approval by the relevant regulatory agencies. Due to the significant risks posed by use of the device, the process of refinement has proven particularly painstaking. Essentially, Abiomed has been attempting to demonstrate the mechanical proficiency of the machine, while at the same time highlighting the device's ability to withstand the rigorous conditions created within human biological settings. In the process, the firm has formulated several tests and standards with regard to each of these areas. Due to the extreme physical demands placed on the AbioCor device, Abiomed scientists were forced to utilize a material capable of bending forty million times a year for twenty years without breaking.¹⁷² Commercially available plastic would surely crack under such stress. This fact led to the development of Angioflex, a proprietary Abiomed material used in the construction of the AbioCor. One test of this material's effectiveness requires the device to pump two hundred million times in a row without failing, namely, enough to sustain human life for five years.¹⁷³ Another particularly interesting test involved placing AbioCor in a bath of salty water for a sustained period time. This test attempted to demonstrate the capacity of the machine's titanium and plastic components for surviving the corrosive effects of blood inside the body.¹⁷⁴ Finally, to gauge the

¹⁷⁰Id.

¹⁷¹Id.

¹⁷²see Transcript, *supra* note 19

¹⁷³Id.

¹⁷⁴Id.

functionality of the AbioCor heart, scientists implanted the device within calves at the Texas Heart Institute. The results of these implants were quite successful, although researchers were somewhat constrained by the fact that the young calves tested quickly outgrew the devices as they began to age.

One climax of Abiomed's rigorous research efforts in the area of total artificial heart technology occurred on December 22, 2000. On that day, Abiomed completed its IDE submission to FDA, requesting regulatory approval to commence initial human trials of the AbioCor Implantable Replacement Heart.¹⁷⁵ The submission of AbioCor's IDE application to FDA represented a significant accomplishment for all parties involved in the product's development, as it was the culmination of countless hours of effort spanning several years.¹⁷⁶ However, this event held special importance for Dr. Lederman in particular. He had, after all, been one of the few persons on the fringe of the research field who had steadfastly weathered the storm of public sentiment following the Barney Clark episode. Lederman noted that "The completion of the AbioCor IDE submission is a major milestone on the path to bringing heart replacement technology to the tens of thousands of people in heart failure who have little hope of receiving a human heart transplant."¹⁷⁷

In an attempt at quickly disseminating knowledge of its research progress in this area, Abiomed chose clinical centers for its prospective trials that spanned the entire United States. These centers included the Brigham and Women's Hospital teamed with Massachusetts General Hospital in Boston, the Texas Heart Institute in Houston, and UCLA Medical Center in Los Angeles.¹⁷⁸ Abiomed further noted that it planned to commence international trials of the AbioCor in various medical centers shortly after clinical trials began in the United States.

Dr Robert T.V. Kung, Abiomed's Chief Scientific Officer, was optimistic about the device's chances at receiving FDA approval for clinical testing. He stated,

¹⁷⁵see "Abiomed Requests", *supra* note 26

¹⁷⁶*Id.*

¹⁷⁷*Id.*

¹⁷⁸*Id.*

Our testing of the AbioCor in preparation for initial human trials has been extensive and the results of this testing have been very encouraging... Subject to regulatory approval, we hope for the first human transplant of the AbioCor to occur in the U.S. during the first half of 2001.¹⁷⁹

Dr Kung noted that prior to receiving FDA approval of the IDE, Abiomed would continue its efforts at producing sufficient quantities of the AbioCor device, while clearing lines of communication with its associates at various clinical centers to ensure that trials would begin quickly and smoothly upon receipt of regulatory approval.

Abiomed was quite candid about the ambitious goals tied to its projected clinical trials. Dr Kung asserted that the trials would attempt to demonstrate that, for certain patients who were experiencing end-stage heart failure and who were not viable candidates for human heart transplantation or other forms of available therapy, use of the AbioCor would provide improved levels of life expectancy along with an acceptable quality of life.¹⁸⁰ At the end of the day, Dr. Kung predicted that “successful completion of clinical trials should generate the clinical data necessary to submit to the corresponding Regulatory Authorities for approval to market the AbioCor in the U.S. and internationally.”¹⁸¹

The optimism exhibited by Lederman and Kung in late December proved to be extremely well founded. On January 31, 2001, a mere month after Abiomed’s submission of its IDE application for AbioCor, the firm announced that it had received permission from the FDA to commence its initial clinical trials.¹⁸² The FDA letter received by Abiomed authorized the firm to undertake implantation of the AbioCor in the first five patients of the slated clinical trial. Authority to implant the device in further patients was reserved by the FDA, which noted that grants of such authority would be predicated on the “success” experienced by the first five transplant patients. Success, according to the FDA, would be based upon periodic review

¹⁸⁰Id.

¹⁸¹Id.

¹⁸²“Abiomed Gets O.K from FDA to Begin Human Implants of Artificial Heart”, January 30, 2001, at <http://www.abiomed.com/about/press/013001.html> (February 23, 2001)

of the patients and the progression of their health conditions. A further factor impacting success would be the patients' quality of life "as measured by a variety of assessment instruments previously validated for end-stage heart failure patients."¹⁸³ The FDA letter of authorization required Abiomed to respond to a number of questions left unresolved in its IDE application, but assured the firm that initiation of clinical trials would not be left contingent upon any responses received by FDA.

The FDA's overall response clearly provided validation for Abiomed and its leaders on a number of levels. Furthermore, the staggeringly quick turnaround time between the AbioCor's application and receipt of IDE approval indicated the intense rigor with which Abiomed's engineers and physicians had approached the process of testing in the pre-clinical stages. Dr Lederman asserted that the IDE application had in fact been "extraordinarily comprehensive, totaling thousands of pages of highly technical material in eighteen volumes."¹⁸⁴ Lederman further noted that one plausible reason for the AbioCor's extremely short turnaround time for approval was rooted within Abiomed's solid relationship and frequent interactions with the FDA's Office of Device Evaluation over the AbioCor's development period.¹⁸⁵ This relationship and familiarity provided the firm with important direction related to the improvement of testing protocols. These improvements, in turn, impressed the FDA and provided it with a degree of confidence when the time came to sanction initial trials in human beings.

Abiomed is currently in the process of making final preparations for the commencement of human trials at its various clinical centers. At the moment, it appears that Dr. Lederman's stated goal of commencing trials during the first half of the current year is close to becoming reality. However, the experiences of prior pioneers in this field of research indicate that Lederman's most important and trying test lies just around the corner. The first patients to receive AbioCor hearts will surely become media darlings, just as Haskell Karp and Barney Clark did decades ago. The success or failure of these patients' implants will surely influence

¹⁸³Id.

¹⁸⁴Id.

¹⁸⁵Id.

the direction and funding of artificial heart research well into the 21st century.

Concluding Remarks

Many important lessons can be gleaned from the experiences of heart surgeons and researchers over the past several decades. One such lesson involves the love-hate relationship between leaders in the field, and members of the media charged with covering high profile experiments. In one sense, pioneers like DeBakey, Jarvik, and Lederman are heavily reliant on the media to promote their path breaking quests to outwit Mother Nature. After all, the public's consciousness regarding the potential contributions that science can make to humanity is heavily influenced by the portrayals that cutting edge technologies receive within the press. Furthermore, public sentiment is one of the most important factors influencing lawmakers charged with the allocation of scarce resources to a seemingly infinite number of worthy research endeavors. The virtue of media coverage is thus twofold: it has the capacity to inform the public about the latest developments within a particular field, and to excite society about the potential future benefits afforded by certain technologies.

However, as the various research episodes chronicled within this paper illustrate, heightened press coverage of particularly notorious experiments has a double-edged quality. If a trial achieves successful results during its fifteen minutes within the spotlight, then the researchers leading it are celebrated within the press, and will likely be rewarded with increased leverage with regard to future funding. On the other hand, if a trial achieves less than spectacular results, its consequences lie in the opposite direction, and are in fact compounded to an exponential degree. Essentially, failed trials lead persons to question not only the merits of particular experiments, but rather the entire field of research underlying them. Further complicating

matters is the fact that heart researchers are held to the most exacting of standards. Although a device may for the most part function effectively, if it doesn't deliver exactly what its proponents promised, then it is considered a complete failure. Thus, results that forward looking physicians and researchers regard as optimistic may be deemed disastrous by lay persons. The uncompromising social standards applied to initial device trials are problematic when one considers the fact that the patients most likely to receive previously untested artificial heart devices are those whose conditions have deteriorated to the point where they are no longer eligible to receive traditional forms of therapy such as allotransplantation. Thus, the deck is effectively stacked against researchers performing these initial trials, in the sense that the slated recipients of experimental devices are patients with high rates of comorbidity, persons likely to succumb to a host of conditions due to the stressful circumstances inherent within heart surgery. Taken together, these factors provide insight into why high profile trials such as those involving Karp and Clark served to chill entire research fields for nearly a decade, despite the important lessons they provided.

The above observations reflect a fundamental tension underlying the field of artificial heart research. Although most members of society are somewhat intrigued by the ability of gifted heart surgeons to sometimes outmaneuver the natural process of dying, most also feel an inherent sense of discomfort when confronted by an approach that so clearly juxtaposes the God-given with the man-made. If a particular trial runs smoothly, then many are likely to overlook the visual spectacle that is necessarily created when artificial devices are merged with the human body. However, if the trial fails, the same group is likely to revert to its intrinsic sense of skepticism toward the field. Scientists once deemed to be pathbreakers are now vilified as out of control renegades. Physicians once regarded as humanitarian healers are now characterized as egotists whose God complexes lead them to compromise the lives of their fellow men and women, all in the name of progress. This duality is clearly encapsulated within a recent piece by Michael Lemonick.¹⁸⁶ Reflecting on

¹⁸⁶see "Reviving Artificial Hearts," *supra* note 77

the amazing potential of devices such as the Jarvik-2000 and the AbioCor, Lemonick nonetheless observes,

Impressive as all of this sounds, nobody is sure what it will be like to live with any of these machines long-term. Maybe technology has merely found a more efficient way to torture heart patients.¹⁸⁷

Despite the significant notoriety that accompanies success in the field of artificial heart technology, the list of those heart pioneers held in high historical esteem remains relatively short. Indeed, some members of this elite group, like DeBakey and Jarvik, are “repeat players” in the sense that their accomplishments span multiple decades and differing technologies. The exclusivity of this club appears to be a function both of the inherent complexity that characterizes artificial heart technology, as well as the unwillingness of otherwise qualified researchers and scientists to enter a field in which they will perpetually be required to walk on eggshells, in the way that heart researchers must. After all, while a failed software program or even an imperfect pharmaceutical product may earn a scientist a certain degree of disrepute, it is unlikely that he or she will ever be accused of playing God.

Researchers who do work up the courage to enter this field must balance the threat of highly visible “failure” against the less visible, yet equally destructive threat of standing still. This observation holds special importance at a time when heart disease continues to flex its powerful might within society, as evidenced by the staggering increase in death rates from cardiac arrest over the course of the 1990’s.¹⁸⁸ Interestingly, history has illustrated that even among the relatively few members of this field, disparate risk profiles abound. For example, in Cooley’s mind, implantation of the Liotta Heart in Haskell Karp represented a reasoned, calculated gamble. To DeBakey, such an experiment was far ahead of its time. In one sense, the case’s ultimate outcome seemed to vindicate DeBakey’s position. Despite the clarity of hindsight, however, Cooley’s central belief in the importance of keeping artificial heart research at the fore of the public consciousness

¹⁸⁸ “Cardiac Arrests Rise In Young Adults During 1990s”, (March 2, 2001), at <http://www.cnn.com/2001/HEALTH/conditions/03/02/cardiac.arrest.ap/index.html> (March 3, 2001)

remains a valid one. If society were to somehow lose interest in the potential benefits of MCSS technology, then researchers in this area would lose access to the public and private funding that they desperately need in order to ensure continued advancement.

Although the most noteworthy points on the timeline of artificial heart technology are experiments that were initially considered failures to at least some extent, much progress has in fact been made over the past half century. Assuming *arguendo* that cutting edge devices like the AbioCor will generate benefits analogous to those of their predecessors, however, several important policy issues remain to be dealt with. The first of these relates to the extremely large cost that is currently associated with artificial heart devices. As these miracles of science continue to proliferate, it is a near certainty that equity issues will begin to assume increasing importance. As the Institute of Medicine (IOM) reported in 1991,

Because of the high cost of MCSSs both individually and in the aggregate...private third-party payers, Medicare, and state Medicaid programs are likely to resist approving coverage for MCSS implantations. The time is ripe for the United States to make clear decisions about access to health care, including costly new technologies.¹⁸⁹

For a variety of reasons, the U.S. has made minimal progress in the area of health care reform over the past decade. Thus, the issues highlighted by the IOM in 1991 remain ripe for resolution.

In addition to the monetary costs associated with the implantation of artificial hearts, society will be forced to shoulder significant additional costs in the form of human capital. As the above procedures become more widely accepted, it is paramount that the available supply of adequately trained personnel, including surgeons, nurses and the like, increase accordingly.

The field of artificial heart technology is unique, in the sense that a great social need for advancement has been met by levels of private sector funding that are inadequate at best.¹⁹⁰ As previously noted, this inadequacy can be explained by the innumerable forms of scientific, economic, and social uncertainty that characterize

¹⁹⁰*Id.*

the development of such devices. Despite these constraints, society has managed to make meaningful progress in this area over the past several decades. In order to ensure that this trend continues, it is paramount that government agencies remain involved in this arena, through formal funding or cost sharing arrangements with parties in the private sector. Furthermore, efforts must be undertaken to ensure that the channels of communication remain open between researchers operating on the cutting edge. Although competition is surely healthy for the industry in some senses, certain forms of collaboration can ensure that wasteful duplication of efforts is kept to a minimum.

The scientific import of the heart, combined with its cultural significance, renders heart research a particularly sensitive area in which to pursue the betterment of society. Nevertheless, pioneers with the courage to plow forward in this field over the last half century have saved countless lives as a result of their unwavering efforts. One thing, however, remains clear. If society is ever to reap the full rewards offered by MCSS technology, it will have to recalibrate its attitudes regarding the field in a more open-minded direction, one that hinges less on short term success, and more on long-term progress. Heroic patients like Barney Clark have accepted this challenge. Time will tell if society at large is capable of doing the same.